



North Carolina State Crime Laboratory

121 East Tryon Road, Raleigh, NC 27603

**Report on Conformance with
ISO/IEC 17025:2005 and FBI QAS Casework
and Database**

Accreditation Assessment Conducted on

May 13- 16, 2013

Lynn Langford, Lead Assessor

Laurette Rapp, Technical Assessors

Laura Kuyper, Technical Assessors

Tina Moroose, Technical Assessors

Tony Tambasco, Technical Assessors

Diane Bode, Technical Assessors

Jim Gannalo, Technical Assessors

David Knoerlein, Technical Assessors

Mark Ahonen Technical Assessors

ANSI-ASQ National Accreditation Board/FQS

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INTRODUCTION

The assessment was conducted against the standards of ISO/IEC 17025:2005/ FBI QAS Casework and Database and any appropriate supplemental requirements *by Lead Assessor Lynn Langford and Technical Assessors, Laurette Rapp, Laura Kuyper, Tina Moroosse, Tony Tambasco, Diane Bode, Jim Gannalo, David Knoerlein and Mark Ahonen.*

The assessment was conducted at North Carolina State Crime Laboratory-Raleigh on May 13-16, 2013 by inspection of facilities; review of policies, procedures, and records; and by staff interviews. All elements of the International Standard were assessed in this assessment.

Places where change is recommended reflect the requirements of program compliance and should not be taken as reflecting the quality of work product. The report is confidential to the customer and is for management purposes only.

The report contains identified non-conformances listed as major, minor, and opportunities for improvement. Each is defined below:

- 1. Major Non-Conformances:** A major non-conformance is the absence of or the failure to implement and maintain one or more of the accreditation checklist requirements or a situation which would, on the basis of available objective evidence, raise significant doubt as to operations or appropriateness of the results reported by the accreditation customer. The assessment team may judge numerous minor non-conformances against a single requirement to be a significant breakdown of the management system and thus a major non-conformance. Any minor non-conformance that is a repeat from the previous assessment will be considered a major non-conformance.
- 2. Minor Non-Conformances:** A minor non-conformance is any other non-conformance which seems to be an isolated occurrence and is normally easily corrected and verified.
- 3. Opportunities for Improvement:** An opportunity for improvement is not a non-conformance or finding. It is used to document items that may help a customer improve their operations.

Cited clause numbers refer to the International ISO/IEC 17025:2005/ FBI QAS Casework and Database and any appropriate supplemental requirements unless otherwise indicated.

The laboratory is required to respond to **non-conformities** in writing within 30 days of receipt of the assessment report. The response shall identify the corrective action taken, including root cause analysis, selection and implementation of corrective action, and any follow-up confirmation of effectiveness. It is recognized that some non-conformities may require more than 30 days for completion of the process of root cause analysis,

selection and implementation of corrective action, and confirmation of effectiveness, and in such instances the 30 day response must include a description of action taken to date and a plan with milestones for completion of the corrective action.

All non-conformities will be verified at the next assessment or surveillance.

No response is required to opportunities for improvement.

All communication on non-conformities must be made through the Lead Assessor and/or the FQS Accreditation Manager.

This report contains the following information, as applicable:

- Confidential and No Conflict of Interest Statement
- Non-Conformances
- Commendations
- Statement on Proficiency Testing, Management Review & Internal Audit
- Conclusions

**ANSI-ASQ National Accreditation Board (ACLASS & FQS) Confidential
Information and No Conflict of Interest Agreement**

I am a designated Assessor and/or Expert and have executed an agreement with ANSI-ASQ National Accreditation Board (ACLASS or FQS, hereinafter the "Company") to provide Accreditation Activities to the Company. As part of such Agreement, I am obligated to execute this Confidential Information and No Conflict of Interest Agreement ("Special Agreement") for each Company's customer for whom I perform Accreditation Activities.

I hereby execute this Special Agreement with respect to North Carolina- Raleigh, I confirm that I have not during the 24 month period prior to the date hereof directly or indirectly provided any consulting or other services which might reasonably be construed as a conflict of interest (e.g., any commercial, financial and other pressures) to or on behalf of Customer. I confirm that I will not during the 12 month period succeeding the last day on which I provide Accreditation Activities with respect to Customer pursuant to the Agreement or any future agreement between the Company and me, directly or indirectly provide any consulting or other services which might reasonably be construed as a conflict of interest to or on behalf (including, but not limited to Accreditation Activities for another accreditation body) to or on behalf of Customer.

I understand that in order to perform Accreditation Activities with respect to Customer, the Company and/or Customer shall provide me, (i) with materials concerning Customer and records of Customer which contain confidential information belonging to Customer, and (ii) with access to Customer's personnel who know confidential information belonging to Customer, which confidential information is not otherwise generally known by the public and which is called "Confidential Information" under this Special Agreement.

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I understand that my obligations under this Special Agreement shall survive the termination of the Agreement.

Designated Assessor:



Date: 05/07/2013

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I hereby execute this Special Agreement with respect to North Carolina State Crime Lab. I confirm that I have not during the 24 month period prior to the date hereof directly or indirectly provided any consulting or other services which might reasonably be construed as a conflict of interest (e.g., any commercial, financial and other pressures) to or on behalf of Customer. I confirm that I will not during the 12 month period succeeding the last day on which I provide Accreditation Activities with respect to Customer pursuant to the Agreement or any future agreement between the Company and me, directly or indirectly provide any consulting or other services which might reasonably be construed as a conflict of interest to or on behalf (including, but not limited to Accreditation Activities for another accreditation body) to or on behalf of Customer.

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Designated Assessor:

Diane W. Bodie

Date:

May 13, 2013

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I hereby execute this Special Agreement with respect to NC Raleigh ("Customer"). I confirm that I have not during the 24 month period prior to the date hereof directly or indirectly provided any consulting or other services which might reasonably be construed as a conflict of interest (e.g., any commercial, financial and other pressures) to or on behalf of Customer. I confirm that I will not during the 12 month period succeeding the last day on which I provide Accreditation Activities with respect to Customer pursuant to the Agreement or any future agreement between the Company and me, directly or indirectly provide any consulting or other services which might reasonably be construed as a conflict of interest to or on behalf (including, but not limited to Accreditation Activities for another accreditation body) to or on behalf of Customer.

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Designated Assessor:

05/07/2013

Laura Key to Nancy Johnson

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I hereby execute this Special Agreement with respect to NC Bureau of Investigation ("Customer").

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Designated Assessor: Anthony Tambasco

Date: 5-13-13

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I hereby execute this Special Agreement with respect to NC SBI ("Customer"). I confirm that I have not during the 24 month period prior to the date hereof directly or indirectly provided any consulting or other services which might reasonably be construed as a conflict of interest (e.g., any commercial, financial and other pressures) to or on behalf of Customer. I confirm that I will not during the 12 month period succeeding the last day on which I provide Accreditation Activities with respect to Customer pursuant to the Agreement or any future agreement between the Company and me, directly or indirectly provide any consulting or other services which might reasonably be construed as a conflict of interest to or on behalf (including, but not limited to Accreditation Activities for another accreditation body) to or on behalf of Customer.

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Designated Assessor:

Jim Gannalo Date:

5 / 9 / 13

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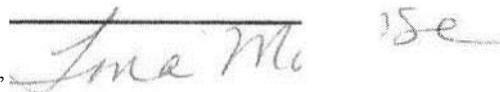
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Date:
5/12/13

Designated Assessor,...



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Designated Assessor:

Date: 4/13/13

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David Knoerlein



Designated Assessor:

Date: 5/12/2013

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Designated Assessor:



Date: 05/13/13

Non-Conformities:

NC ELL-13-01

ISO 17025

4.1.5.f

4.1.5.i

4.1.5.j

Minor

The laboratory has defined the role of each position but the organizational chart does not make reference to which duties are being carried out by whom

The QM nor the QCO positions are named on the organizational chart

Deputies for key managerial positions have not been appointed.

NC ELL-13-02

ISO 17025

4.3

4.3.1

Minor

The forms and instrument manuals that form a part of its management system are not being controlled with version number and issue date and are not on the master list of documents.

NC ELL-13-04

ISO 17025

4.14

4.14.1

4.14.1 F-5 FQS

Minor

North Carolina's QM p20 of 51 states that an internal audit will be conducted at least once per calendar year, the internal audits are being conducted; however, the lab has not established a pre-determined schedule which designates at least the month of the scheduled function.

4.14.1 F-5 FQS

The internal audits are being conducted annually; however a predetermined schedule that designates the month of the scheduled function has not been identified.

NC ELL-13-05

ISO 17025

4.15

4.15.1

4.15.1 F-6

Minor

North Carolina's QM p21 of 51 states that a management review will be conducted at least once per calendar year, these reviews are being conducted; however, the lab has not established a pre-determined schedule which designates at least the month of the scheduled function.

4.14.1 F-6 FQS

The management reviews are being conducted annually; however a predetermined schedule that designates the month of the scheduled function has not been identified.

NC ELL-13-07

ISO 17025

5.5

5.5.8

Minor

The post amplification equipment in the DNA casework and database labs are not labeled indicating calibration status.

NC ELL-13-08

ISO 17025

5.6

5.6.1

Minor

No reference to ensure accuracy of measuring device for impressions.

NC ELL-13-09

ISO 17025

5.8

5.8.2

QAS 7.1.1.c Casework and Database

Minor

During lab observation labeled trays containing tubes with amplified product were examined and found to be not labeled appropriately. The laboratory's Procedure for PCR Amplification for Casework and database (v1 effective 12/31/12) states in section 5.5 page 1, the following: Label the appropriate number of PCR reaction tubes (individual or strip) and place them in an amplification tray for the 9700 thermal cycler. The tubes shall be labeled to permit the Forensic Scientist to determine the sample contained in each tube.

NC ELL-13-10

ISO 17025

5.4.6.2

Minor

The laboratory reports a quantitative value for their blood alcohol cases, but has not determined what the uncertainty of measurement is for this process.

NC ELL-13-11

ISO 17025

5.4.6.3

Minor

The laboratory has not determined what the uncertainty of measurement is for blood alcohol calculations and could not articulate the components that contribute to the uncertainty of measurement at the time of the assessment.

NC ELL-13-12

ISO 17025

5.10.3 c

Minor

The laboratory does not currently have the uncertainty of measurement determined for the blood alcohol procedure and as such are unable to provide uncertainty of measurement information on their reports.

Opportunities for Improvement:

OFI ELL-13-03

ISO 17025

4.13

4.13.1.2

Retention times of records are located in each individual procedure, it was time consuming and labor intensive to find all the time periods.

OFI ELL-13-06

ISO 17025

5.2

5.2.2

Although continuing education was available for review it was difficult to assess the 8 hour requirement for each Forensic Biology/DNA analyst because continuing education was listed by month and not individual analyst.

OFI ELL-13-13

ISO 17025

5.6.3.3

During the employee interviews, it was revealed that the laboratory is in the process of using a set of primary weights to verify the performance of secondary weights throughout the laboratory. While, the weights are not out of compliance yet, this procedure needs to be completed and implemented to ensure continued compliance before the weights currently in use need to be verified again.

OFI ELL-13-14

ISO 17025

5.10.3 c

The drug chemistry unit includes the uncertainty of measurement on their reports; however, identifying the confidence level and the k factor used in the calculation should be added to the

spreadsheet in the discovery packet to enable the customer to use the information provided accurately.

OFI ELL- 13-15

ISO 17025

5.4.1 General

The technical procedure for the examination of arson evidence states that the “ASTM procedures and classification shall be used as a guide for flammable/combustible liquid identifications”. The laboratory does have one electronic media version of the current ASTM documents housed with the Quality Assurance Manager. The arson analysts are using older paper versions in their work area. If the documents were made a controlled document and housed on the network drive they would definitely be more readily available.

OFI ELL -13-16

ISO 17025

5.5.2 F-33 FQS requirement

A voltmeter performance check is described in the technical procedure for the examination of headlight and bulb evidence. No lamp cases have been conducted since the version 1 effective date of 09/17/2012. The 2012 lamp proficiency and two older lamp cases were reviewed and the performance check was not documented in the case record. A method of documenting this performance check similar to the other performance checks in trace might help with the future documentation of lamp cases.

COMMENDATIONS

The Assessment Team would like to thank the Laboratory staff for their openness and willingness to provide the requested materials necessary to conduct an efficient assessment, both before and during the audit. The Laboratory is commended for having a clear commitment to quality, stemming from top management to all the analysts and staff. The quality assurance program is comprehensive and the documentation is concise and well organized.

PROFICIENCY TESTING, MANAGEMENT REVIEW, AND INTERNAL AUDIT

The Laboratory has records for successful participation in Proficiency Testing in conformance with FQS requirements. In addition, the Laboratory has successfully conducted internal audits and management reviews in 2012 in conformance with ISO/IEC 17025:2005.

CONCLUSIONS

The non-conformities identified should be easily remedied. The quality assurance program is comprehensive and the documentation is thorough and well written. The staff is qualified and appropriately trained. The facilities are safe and properly equipped.

To appeal any non-conformity cited in this report, please submit your appeal according to the FQS appeals procedure, no later than ten (10) days following your receipt of this report from FQS. The justification for the appeal and the change that the laboratory is seeking must be clearly stated.

Responses to FQS are due by July 1, 2013, unless otherwise arranged.

Respectfully Submitted,

A handwritten signature in cursive script, reading "Lynn Langford".

Lynn Langford
Lead Assessor
ANSI-ASQ National Accreditation Board/FQS